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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,088

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Shigenori Kuga

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02/25/2008

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EXAMINER

LAU, JONATHAN S

ART UNIT

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1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,088	Applicant(s) KUGA ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6 pg/ 03May2006, 09Oct2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is the national stage entry of PCT/JP05/07349, filed 08 Apr 2005; and claims benefit of foreign priority document JAPAN 2004-132880, filed 28 Apr 2004; currently an English language translation of this foreign priority document has not been filed.

Claims 1-14 are pending in the current application. Claims 8-14, drawn to non-elected inventions, are withdrawn. Claims 1-7 are examined on the merits herein.

Election/Restrictions

Applicant's election without traverse of the invention of Group I, claims 1-7, in the reply filed on 23 Jan 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 Jan 2008.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-5 encompass a naturally occurring

Art Unit: 1623

article, a naturally occurring chitin-protein complex as disclosed by McCandliss et al. (US Patent 4,536,207, issued 20 Aug 1985, cited in PTO-892) (column 1, lines 13-14). As evidenced by Falini et al. (Tissue Engineering, 2004, vol 10, p1-6, cited in PTO-892), chitin from mollusk shells is in the form of β -chitin, sandwiched between protein layers to form an inclusion complex (page 2, left column, lines 8-13). McCandliss et al. discloses the complex is dried at 100 °C, indicating the naturally occurring complex has a melting point of at least 100 °C, a limitation of instant claim 1. It is inherent that a protein is an organic compound, a limitation of instant claim 2, that contains at least oxygen and nitrogen, a limitation of instant claim 3, in the form of carboxyl and amino groups, and amide bonds, a limitation of instant claims 4 and 5. McCandliss et al. does not describe the chitin-protein complex with the terminology of an inclusion compound, but does disclose the chitin-protein complex provides a source of nitrogen in slow-release form (abstract), a property of inclusion compounds.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by McCandliss et al. (US Patent 4,536,207, issued 20 Aug 1985, cited in PTO-892) as evidenced by Falini et al. (Tissue Engineering, 2004, vol 10, p1-6, cited in PTO-892).

McCandliss et al. discloses a naturally occurring chitin-protein complex (column 1, lines 13-14). McCandliss et al. discloses the material is prepared from suitable chitin-containing material biomass raw material, for example mollusks (column 5, lines 38-43). As evidenced by Falini et al., chitin from mollusk shells is in the form of β -chitin, sandwiched between protein layers to form an inclusion complex (page 2, left column, lines 8-13). McCandliss et al. discloses the complex dried at 100 °C, indicating it has a melting point of at least 100 °C, addressing instant claim 1. It is inherent that a protein is an organic compound, addressing instant claim 2, that contains at least oxygen and nitrogen, addressing instant claim 3, in the form of carboxyl and amino groups, and amide bonds, addressing instant claims 4 and 5. McCandliss et al. discloses the protein functions as an antibiotic with nematostatic and nematocidal activity (column 4, lines 20-22), addressing instant claim 7. McCandliss et al. does not describe the chitin-protein complex with the terminology of an inclusion compound, but does disclose the chitin-protein complex provides a source of nitrogen in slow-release form (abstract), a property of inclusion compounds.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drohan et al. (US Patent 6,124,273, issued 26 Sep 2000, cited in PTO-892) in view of Kim et al. (Journal of Polymer Science: Part B: Polymer Physics, 1996, 34, p2367-2374, cited in PTO-892).

Drohan et al. discloses a supplemented chitin hydrogel (column 6, lines 25-27) wherein the chitin serves as a carrier vehicle for "growth factors, analgesics, antimicrobial compositions, anti-inflammatory compounds, antibodies, anticoagulants, antiproliferatives, cytokines, cytotoxins, chemotherapeutic drugs, interferons, hormones, hydroxyapatite, lipids, oligonucleotides, osteoinducers, polymers, polysaccharides,

Art Unit: 1623

proteoglycans, polypeptides, protease inhibitors, proteins (including plasma proteins), steroids, vasoconstrictors, vasodilators, vitamins, minerals, stabilizers and the like, for a prolonged period of time” (column 9, lines 35-45), addressing instant claim 7. Drohan et al. discloses “supplemented” to mean the supplementary compound, or guest compound, may be mixed with the chitin components in liquid form prior to hydration or added to the hydrogel as the matrix sets up after hydration (column 12, lines 24-26) and a “matrix” to mean the structural properties or architecture of a solid or semi-solid (including a hydrogel) in which other components may be cast, mixed, dispersed or dissolved (column 12, lines 55-58). It is inherent that a polysaccharide is an organic compound, addressing instant claim 2, that contains at least oxygen, addressing instant claim 3, in the form of hydroxyl groups and ketal bonds, addressing instant claim 4, and that it possesses a plurality of hydroxyl functional groups, addressing instant claims 5 and 6. Drohan et al. does not describe the supplemented chitin hydrogel using the terminology of an inclusion compound, however a polysaccharide cast, mixed or dispersed in a chitin hydrogel matrix meets this description. Drohan et al. specifically disclose complexes of chitin and ciproflaxin (melting point 255 - 257 °C), tetracycline (melting point 170 - 173 °C) and ampicillin (melting point 208 °C) (column 31, lines 42-45, addressing the melting point limitation of instant claim 1.

Drohan et al. does not specifically disclose the chitin to be β -chitin.

Kim et al. teaches β -chitin will be a good candidate material for uses in medical implant devices, wound dressings, drug delivery, and so on (page 2368, left column, lines 13-17).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Drohan et al. with the teaching of Kim et al. of the specific chitin β -chitin. Drohan et al. discloses chitin is a material that is biocompatible and naturally resorbed by the body, and has been previously used for sustained drug release, bone induction and hemostasis (column 1, lines 20-22). Drohan et al. discloses "Any chitin or its derivative, such as a commercially available chitosan, may be used in some embodiments of this invention. For these uses, such as localized drug delivery, the particular composition of the selected chitin or derivative is not critical as long as it functions as desired." (column 18, lines 56-60) Kim et al. teaches β -chitin will be a good candidate material for drug delivery, providing motivation for one of ordinary skill in the art at the time of the invention to combine the invention of Drohan et al. with the teaching of Kim et al. of β -chitin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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